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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,366	07/10/2006	Matthias Kraemer	P70978US0	5554

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

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11/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,366	KRAEMER, MATTHIAS	
	Examiner	Art Unit	
	Philip R. Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/28/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

In the amendment filed 10/28/09, applicant amended claims 1, 3, 4, 7, 9, 10, and 13, and cancelled claim 5. Claims 1-4 and 6-3 are currently pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaldon et al. (US 6,284,141) in view of Bosetto et al. (US 6,793,827).

2. With respect to Claims 1, 3, and 4, Shaldon discloses a blood treatment device comprising a dialysis filter having two chambers separated by a semi-permeable membrane 8. The first chamber is part of a dialysis circuit having a dialysis fluid inlet and an outlet, and the second chamber is part of an extracorporeal blood circuit having a blood inlet and outlet. See Figure 4. The system further comprises a sensor (10, 11, 12) connected to a computer 14, said computer 14 being adapted to determine the concentration of a substance in the blood. The computer is configured to maintain the concentration value within a specified range (i.e. threshold) and modifies the operation of the system when the sensed concentration value is abnormal (Column 6, Lines 20-

28). Shaldon further teaches that the system is *capable* of calculating the urea transfer rate of the substance and total quantity of the substance withdrawn based on the sensed urea concentration (Column 5, Lines 54-63 and Column 7, Lines 27-40). The analyzer unit has an admissible value range for the concentration, such that it is configured to inform the control unit that the device is performing properly and make appropriate changes when the value is outside the desired ranges (Columns 5 and 6) (see Figure 2, for example).

Shaldon, however, does not specifically teach that the concentration, flow rate, and total fluid removed are *all* calculated and compared to threshold values to control the system, that the system comprises both an analyzer unit *and* a control unit, or that the substance whose concentration is detected is potassium.

Regarding Shaldon's failure to specifically teach that concentration, urea flow rate, and total urea removed are *all* calculated and compared to threshold values to control the system, Shaldon teaches that the computer is configured to maintain the concentration value within a specified range and modifies the operation of the system when the sensed concentration value is excessively high or low (Column 6, Lines 20-28). Additionally, Shaldon teaches that urea flow rate and total quantity of urea removed are proportional to the sensed concentration, and may be calculated continuously by the computer based on the concentration and dialysis fluid flow rate (Column 5, Lines 54-63 and Column 7, Lines 27-40). Because the urea flow rate and total urea are proportional to the sensed concentration value, they may be used by the computer as alternate indicators for controlling the rate of transfer between the blood

and dialysis fluid. Shaldon, therefore, clearly suggests that concentration, flow rate, and quantity removed may all be monitored and controlled in order to optimally control the dialysis system. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Shaldon to detect, monitor, and maintain the concentration, flow rate, and quantity of urea removed from the blood within admissible value ranges, in order to provide additional means for ensuring that the proper concentration and amount of urea has been removed from the blood through dialysis procedure.

Regarding Shaldon's failure to specifically teach a separate analyzer and control unit, the computer 14 disclosed by Shaldon is configured to receive and analyze data, and control the system based on said data. The computer, therefore, functions in the same manner that a separate analyzer and controller would function. It would have been obvious to one of ordinary skill in the art at the time of invention to separate the computer of Shaldon into a separate analyzer and controller because doing so would not change the functionality of the device. See MPEP § 2144.04.

Regarding the substance that removed, Bosetto discloses a dialysis system comprising a potassium sensor downstream of the dialyzer. Optionally, the system may also comprise a potassium sensor upstream of the dialyzer (Column 7, Lines 18-22), such that the difference between the potassium concentrations upstream and downstream of the dialyzer may be accurately measured, thereby allowing the controller to accurately determine the exact amount of a substance being transferred into or out of the blood. Furthermore, the sensors are linked to the controller, such that the speed of

the pumps can be automatically varied, such that the removal rate of potassium may be controlled according to a specific user profile (Column 6, Lines 19-40). Specifically, the use of multiple potassium sensors allows for the treatment of uremic patients by removing excess potassium from the blood (Column 1, Lines 37-53), and maintaining blood potassium concentrations at a specific level. This method of preventing hyperkalemia and hypokalemia is well established in the art of blood treatment. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the dialysis system of Shaldon with the upstream and downstream potassium sensors of Bosetto in order to accurately remove a specific amount of potassium from the blood, thereby preventing diseases such as hyperkalemia.

3. With respect to Claim 2, Shaldon teaches at least one sensor (12) is provided in the dialysis fluid outlet line for determining the concentration of the substance.

4. With respect to Claim 6, Shaldon teaches that the transfer rate value range extends from zero to a user-defined maximum value (i.e. "limit value").

5. With respect to Claims 7 and 8, Shaldon's computer 14 controls the system such that a target value (i.e. "desired dose") of the substance is withdrawn (Column 8, Lines 1-7). A time-controlled ending can be programmed, thereby allowing the treatment to take a specific amount of time to complete.

6. With respect to Claim 9, Sheldon and Bosetto disclose the device substantially as claimed. Bosetto further disclose that the quantity of potassium eliminated during

treatment depends directly on the difference between the concentration of potassium in the blood and the concentration of potassium in the dialysis fluid (Column 1, Lines 38-64). Once the concentrations in the blood and dialysis fluid are equal, transfer across the membrane will effectively cease. Controlling a dialysis system in this manner is well known in the art. Therefore, it is obvious that the controller controls the system such that the potassium concentrations of the dialysis fluid and blood will be equal when the process is complete, thereby preventing additional potassium removal from the blood.

7. With respect to Claims 10-12, Shaldon discloses a plurality of sensors, including flow rate sensors and a concentration sensor. The sensors allow the computer to reduce the blood concentration at an efficient rate (i.e. lowering the blood concentration at the maximum possible transfer rate). The computer determines the concentration and flow rate of the targeted substance (see above). Once determining these values, the computer compares the concentration to the targeted concentration value and compares the flow rate to the targeted flow rate value. Shaldon, however, does not specifically disclose a concentration sensor upstream of the dialyzer for determining the concentration upstream before the exchange. Bosetto discloses a dialyzer that has upstream and downstream potassium sensors for determining the concentration of potassium in the fluid. The controller uses the concentration readings from these sensors to determine the amount of potassium removed from the blood via the dialyzer. Based on the readings from the sensors, the desired concentration, and the desired flow rate, the controller is capable of optimizing the system parameters to remove

potassium from the blood as efficiently as possible based on a series of characteristics curves (see Figure 3) (Column 6, Lines 9-57). It would have been obvious to one of ordinary skill in the art at the time of invention to use the system with multiple flow sensors of Shaldon with the multiple potassium sensors of Bosetto in order to allow for concentration and flow rate measurements at any point in the flow path. The addition of these sensors would increase the overall accuracy of the system, thereby, allowing the controller to remove the targeted substance as quickly as possible. By adding an upstream concentration sensor to the Shaldon device, it would be *fully capable* of performing the intended function.

8. With respect to Claim 13, Sheldon and Bosetto disclose the system substantially as claimed (see above). Shaldon, however, does not specifically disclose that the system comprises an input device. Bosetto further discloses an input device 32 for inputting reference values into the dialysis system's computer. These reference values are then used in calculations related to the operation of the device (column 6, Lines 9-57). It would have been obvious to one of ordinary skill in the art at the time of invention to modify device of Shaldon with the input device of Bosetto in order to allow the user to input more information about the characteristics of the flow paths, thereby allowing for more accurate calculations and allowing the system settings to be tweaked for each individual patient (Column 6, Lines 9-26).

Response to Arguments

Applicant's arguments filed 10/28/09 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to combine the Shaldon and Bosetto references. Specifically, applicant argues that the devices of Shaldon and Bosetto function differently because the specific rate of urea extraction is not important, while potassium concentration must be constantly regulated (page 8 of arguments). Additionally, applicant argues that Bosetto is silent with regard to monitoring of the transfer rate (page 10).

These arguments have not been found persuasive because both Shaldon and Bosetto clearly teach the use of profiles to control the rate at which the desired substance (urea or potassium) is withdrawn. Specifically, Shaldon teaches the use of characteristic curves to change the removal rate of urea over time, such that the rate of urea removal is maximized subject to the patient's ability to withstand treatment. Additionally, Bosetto clearly teaches that the controller can be used to control potassium levels based on either a fixed reference value or a *stored variation profile* (Column 6, Lines 19-26). The control unit controls the speed of the pumps in response to concentration data received from the sensors and a reference value stored in the profile, *thereby actively controlling the removal rate of potassium from the blood*. The control unit then adjusts the speed of the pumps in order to match the sensed concentration value to the reference concentration value (Column 6, Lines 27-40). Therefore, Bosetto's device functions similarly to that of Shaldon, but controls the removal rate of potassium instead of urea. It is the examiner's opinion that one of

ordinary skill in the art at the time of invention would have recognized that Shaldon's device could be used to remove potassium at a controlled rate, as suggested by Bosetto, in order to prevent diseases such as hyperkalemia from occurring as a result of dialysis treatment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
19 November 2009